97TH CONGRESS } HOUSE OF REPRESENTATIVES { REPT. 97-777
2d Session } { Part 1

HUMANE CARE AND DEVELOPMENT OF SUBSTITUTES FOR ANIMALS IN RESEARCH ACT

AUGUST 19, 1982.—Ordered to be printed

Mr. FUQUA, from the Committee on Science and Technology, submitted the following

REPORT

together with

DISSENTING VIEWS

[To accompany H.R. 6928 which on August 4, 1982, was referred jointly to the Committee on Energy and Commerce and the Committee on Science and Technology]

[Including cost estimate of the Congressional Budget Office]

The Committee on Science and Technology, to whom was referred the bill (H.R. 6928) to promote the development of nonanimal methods of research, experimentation, and testing, and to assure humane care of animals used in scientific research, experimentation, and testing, having considered the same, reports favorably thereon with an amendment and recommends that the bill, as amended do pass.

H703-14

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PURPOSE OF THE BILL

The purpose of the bill is 1) to encourage the development of research and testing methods that do not use animals or that reduce the numbers of animals used, 2) to establish a framework for uniform humane standards for care and treatment of animals used in research and testing, and 3) to increase awareness of, and considerations for minimizing pain caused research animals.

I. SUMMARY

Legislative history

Since the enactment of the Animal Welfare Act in 1966, and subsequent amendments (7 U.S.C. 2131–2156), no law dealing specifically with laboratory animals has been passed by the Congress.

Beginning with the 92nd, resolutions and bills have been introduced in each Congress to promote development of methods of research and testing that would not use animals or that would use fewer animals

and cause a consequent reduction of pain and suffering to animals.[1]

During the 96th Congress a House Concurrent Resolution and 4 bills were introduced, 4 of which dealt with promoting development of research methods to minimize use of live animals and one that would amend the Animal Welfare Act to insure humane treatment of laboratory animals.[2] The bills were referred to the Committee on Science and Technology, jointly to the Committees on Science and Technology and Interstate and Foreign Commerce, and in the case of the bill to amend the Animal Welfare Act, jointly to the Committees on Agriculture, Interstate and Foreign Commerce, and Science and Technology.

No action had been taken on any of the bills. However, interest in the subject built steadily, and the Committee's Subcommittee on Science, Research and Technology, to whom the bills were referred, began a serious study of the issue.

In 1980, the Subcommittee encouraged the National Institutes of Health in its planning for a conference to assess the state-of-the-art of research and testing methods that do not use animals. When the NIH-sponsored symposium, "Trends in Bioassay Methodology: *In vivo*, *in vitro* and Mathematical Approaches," was held in Washington on February 18–20, 1981, the Subcommittee chairman presented opening remarks.

The bills that had been pending in the 96th Congress were all reintroduced during the 97th Congress.[3]

Of these bills, two emerged as the most strongly supported and the most controversial. The first (H.R. 556), known as the "Research Modernization Act," called for establishment of a National Center for Alternative Research within the National Institutes of Health composed of representatives of each Federal agency which conducts or sponsors research and testing which uses animals. The Center would carry out the Act's purpose to increase the use of existing alternatives to the use of live animals in research and testing and to encourage the development of more such alternatives; to provide for training of scientists in the use of methods of research and testing which do not use live animals; to eliminate duplication of research and testing on live animals; and to disseminate information on alternative methods of research and testing which do not involve use of animals. Funding for the Act would be accomplished through directing to the development of alternative methods of research and testing, by each agency represented in the Center, 30 percent to 50 percent of all appropriations made available to such agency for research and testing programs involving use of animals.

The proponents and supporters of H.R. 556 saw it as a way to accomplish the desired goals without asking for new money. Others, particularly the research community and the agencies sponsoring such research, while agreeing with the purposes of the bill, perceived the redirection of sizable amounts of appropriated research funds to be a threat to ongoing research programs.

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[1] 92d Cong., H. Con. Res. 243 and 296; 93d Cong., H. Con. Res. 40, 152, 292, 340, and 404 (all identical); 94th Cong., H. Con. Res. 42, 87, 229, and 410; 95th Cong., H. Con. Res. 130, and H.R. 2448, 9060, 10484, 11374, 12332, 13707, and 14240 (all identical).

[2] H. Con. Res. 26, H.R. 282, 4479, 4805, and 6847.

[3] H. Con. Res. 38, H.R. 220 and 2110 (identical), 556, and 930

The second bill (H.R. 4406) called for amending the Animal Welfare Act to assure humane treatment of laboratory animals. It set out detailed standards for care, treatment and use of such animals, including specific provisions concerning use of pain killers when animals are used in experiments involving pain.

On October 13 and 14, 1981, the Subcommittee on Science, Research and technology held hearings on the use of animals in medical research and testing. The purpose of the inquiry was to examine:

1. Excessive, unnecessary, uneconomic or inappropriate use of animals in current practice;
2. Ways to promote more humane and appropriate use of animals, including alternatives to animal use where possible;
3. Incentives for development of more and improved alternative to animal use, including those suggested in pending legislative proposals;
4. Responses from academic, private and public research institutions to problems raised by those proposals; and
5. Areas in which animal-based research or testing remains crucial to protection or enhancement of human health.

Testimony was taken from Members of Congress, government witnesses, the National Research Council, private industry, animal welfare spokesmen and the research community.

At the hearings, the Subcommittee chairman stated his intent to formulate Subcommittee legislation using the hearing record and idea from pending bills, in the hope of developing a bill that could be supported both in and out of Congress.

The process of drafting a bill covered a span of several months, was a bipartisan effort, and included a continuing discussion of evolving drafts with leaders of both the animal welfare and scientific communities.

Committee actions

On April 29, 1982, the "Humane Care and Development of Substitutes for Animals in Research Act" (H.R. 6245) was introduced, sponsored by 8 members of the Committee on Science and Technology.

The Subcommittee held a hearing on May 4 at which government witnesses testified on the new bill. At a meeting of the Subcommittee on June 9, H.R. 6245 was amended, approved by a 14–1 vote, and sent to the full Committee.

The full Committee met and considered the Subcommittee approved version of H.R. 6245 on August 3, when a bill reflecting Committee actions was ordered to be prepared and introduced. This "clean" bill, numbered H.R. 6928, was introduced on August 4 and ordered reported from the full Committee by a voice vote, on August 11, a quorum being present.

II. BRIEF EXPLANATION OF THE BILL

The "Humane Care and Development of Substitutes for Animals in Research Act" seeks to address in one bill the interest and concerns expressed in several legislative proposals over the past several years.

The bill has three main thrusts:

1. It places special emphasis on the development of methods of research and testing that do not require live animals, that reduce the number of animals used, and produce less pain and distress in animals used.

2. It seeks to assure uniform, humane treatment, care and use of laboratory animals by requiring a rigorous standard for accreditation of research entities which are federally funded, and mandates an animal care committee within each research entity, which committee shall include a veterinarian and a member not affiliated with the research entity.

3. It requires scientific peer reviewers to make sure that research proposals include appropriate provision for minimizing pain and distress in animals used. Reviewers also must evaluate proposals in terms of the importance of expected benefits from the research as it relates to any animal distress involved in the experimentation.

In Title I, the Secretary of Health and Human Services is authorized to make awards for the development of nonanimal methods of research and testing, sometimes referred to as "alternative" methods. Such awards will be funded from research resources made available within the Department of Health and Human Services.

Any proposal considered for funding under this title must have been assessed through appropriate peer review. An Advisory Panel shall be designated by the Secretary to advise him concerning his responsibilities under this title. The Panel will work out a system for assuring that proposals meeting the requirements of this title will receive full consideration for funding by all appropriate programs of the Department of Health and Human Services or for funding under resources made available under this title.

This title also provides for promotion by the Secretary, through coordination with appropriate regulatory groups and agencies, of improved testing methods. The Secretary will direct the National Toxicology Program to significantly increase its resources for R&D on new methodologies and validation of nonanimal research and testing methods. A progress report is called for in two years and biennially thereafter.

Title II is concerned with assuring uniform standards for care and treatment of animals used in research and testing, and establishes a framework for accomplishing this. In order to receive Federal funding for research involving the use of large numbers of animals, a research entity must be accredited by a private agency or agencies designated by the Secretary of Health and Human Services. "Large numbers of animals" is specified in the Act as meaning 100 for rodent species, 10 for non-rodent species, and 1 for non-human primates. The standards for accreditation shall be at least comparable to the best of current practices as stated in the NIH Guide for the Care and Use of Laboratory Animals.

Full accreditation may be achieved over a period of 10 years as far as needed structural changes and modernization of facilities are concerned, and a research entity may be provisionally accredited if it demonstrates satisfactory progress toward the 10 year goal. However, during the interim period the entity must meet standards for animal care and treatment under the existing Animal Welfare Act, and must comply with appropriate requirements for feeding, watering, shelter, exercise, etc., and acceptable procedures of anesthesia set forth in this Act.

The research entity must maintain an animal studies committee which is to include a veterinarian and a member not affiliated with the

research entity. Among other duties, the commmittee will make semi-annual inspections of all animal facilities, and will review ongoing research to assure that animals are treated and used with appropriate care and handling. The committee will certify to the responsible Federal agency that inspections have taken place, and report any violations of assurances required in the bill. The reports will be signed by a majority of the committee, with minority views attached if desired, and particularly by the veterinarian or non-affiliated member if either has not signed the majority report.

The other main thrust has to do with raising awareness of researchers and scientific peer reviewers with respect to pain caused animals used in research and testing. Certain assurances and justifications are set out that peer reviewers must look for in research proposals involving the direct use of conscious animals. These include appropriate provision for involvement of a veterinarian; proper use of anesthetics and analgesics, or justification for withholding them when scientifically necessary; provision for appropriate pre- and post-surgical medical and nursing care; and assurance that, except for reason of scientific necessity, no animal will be used in more than one major operative procedure from which it is allowed to recover.

Discussion of major issues and the Committee's intent with regard to them can be found in the "Committee Views" which follow.

III. Committee Views

1. Development of improved research and testing methods (title I)

The Committee's intent with this Title is to ensure that progress is made as rapidly as possible in development of research and testing methods which avoid or minimize the use of animals. It feels that there is sufficient promise in these methods, in terms of improved speed, economy and accuracy in research and testing, that their development should be singled out as a clear and distinct mission of NIH, working in cooperation with other appropriate regulatory and scientific research agencies. It is the purpose of this Title to single out and provide a specific Congressional mandate for that mission.

The purpose of the Advisory Panel is to advise the Secretary of specific opportunities for progress in this area, and on setting up a system to ensure that peer-reviewed proposals to develop non-animal research and testing methods receive proper funding review in accordance with the goals of this section. The Advisory Panel is given a specific role in the process because of Committee concern that interdisciplinary or novel proposals for improved methodologies may not receive recognition appropriate to their importance when considered against priorities of a mission or discipline-oriented study section or other revew processes. While insisting that the function of the Advisory Panel must not be such as to interfere with the NIH peer review process, the Committee does want to make clear that it wishes the Advisory Panel to work out effective systems to expedite research in this area. Such a system should not encourage researchers to avoid opportunities for funding under existing programs, or encourage funding for substandard proposals, but simply ensure that proposals with real opportunities for progress, but lack of access to funding under

conventional research programs, are not neglected. The system should include a communication mechanism to insure that approved and promising proposals may be brought to the attention of all programs within the Department of Health and Human Services, or within other federal agencies, so that these proposals can be considered where they best match funding priorities or where supporting funds are most available.

The Committee intends that the Secretary have the flexibility in establishing the Advisory Panel to either make it part of an existing committee or panel, or create a new body, as he deems most effective and efficient. However, the Committee does want to make clear that adequate resources and authority should be provided to the Panel so that it can effectively carry out its responsibilities under Title I, and that it should meet no less than semiannually. The Committee stresses that the Panel should include members who are recognized experts in fields such as the following: mathematical modeling; cell, tissue, or organ culture, or combination thereof; statistical analysis; molecular toxicology; robotics and biomedical engineering; behavioral science, clinical human and veterinary medicine; and other relevant scientific disciplines. The observations, recommendations, and experience of the Panel in assisting the Secretary in expediting research under the mandate of Title I should be an important part of the report required under Section 102(c). The funds made available by the Secretary for fiscal year 1983 in this section may be reasonably set at or near the current level of effort at HHS and should not be construed to imply a requirement for large amounts of new funding. The Committee also recognizes that much progress in development of improved research and testing methods has come as a by-product of unrelated basic research, and expects that these opportunities should continue to be an important part of the efforts to develop alternatives to animal use. It is expected however, that the Secretary will provide specific funding in fiscal years 1984 and 1985 which expands these efforts as research opportunities unfold. The Committee does not want to suggest that arbitrary amounts be expended in this area in the absence of real indicators of progress. It does, however, want to ensure that specific funds so designated are sufficient to insure that actual appropriations in this area can be available as rapidly as scientific opportunities unfold.

The Committee does not intend, by expanding funding in this area, to detract from support for other important research activities of HHS. Wisely administered, this section should, in contrast, enhance the long-run funding for other HHS activities. This is simply because non-animal research and testing techniques are very often more economical than the expensive and elaborate systems needed to support animal experimentation. The investment in development of less expensive non-animal techniques should enhance rather than detract from the over-all resources of HHS for health-oriented research.

The Committee also wants to emphasize the importance of opportunities for development of improved methodology under the mandates of the National Toxicology Program. Clearly the greatest opportunity for both over-all economy, and reduction of animal use, occurs in repetitive testing. The Committee encourages the Secretary

to draw on the coordinated resources of the various regulatory and scientific research agencies in seeking progress in this important area.

The Committee recognizes that to give a well-defined focus and thrust to the non-animal research and testing program it may be desirable shortly to place the lead responsibility under NTP. It is true that historically, many of the most significant developments (Ames test, neurological models, etc.) have come from the basic science supported by NIH, and the NIH has taken the lead in focusing scientific attention on this area with its February 1981 symposium: "Trends in Rioassay Methodology". For this reason the Committee specifically does not want to interrupt that momentum by causing bureaucratic difficulties related to shifting current responsibilities. The Committee does intend, however, that as the integrated, interagency efforts of the NTP mature, the Secretary should consider use of that program as the lead and coordinating vehicle for exploiting technical opportunities to develop methodologies reducing the number of animals in research and testing.

2. Relationship of H.R. 6928 to the Animal Welfare Act (title II)

It is intended by the Committee that the Animal Welfare Act remain as an important statutory minimum requirement for research animal care, transportation, sale, etc. Its penalties, fully enforced by governmental agencies, can be relied on as a legal mechanism to avoid the most serious abuse of proper laboratory animal treatment, above and beyond the cessation of federal research support as specified in this act. In addition, the Animal Welfare Act provides important coverage of private (non-federally funded) research or other facilities not covered in this bill.

However, for optimal facility design and investment, research entities generally respond most favorably to peer-designed and operated accreditation mechanisms. Thus, it is the intent of this bill to direct research entities into quality accreditation programs for anmal facilities and programs in order to enhance the quality of care, treatment, and use of animals in research and testing beyond the legally enforceable minimum standards of the Animal Welfare Act.

The Committee intends that the Secretary of Health and Human Services will work closely with the Secretary of Agriculture to insure maximum coordination of efforts by the designated accrediting agencies and the Animal and Plant Health Inspection Service (APHIS) in order to most effectively use the limited resources of APHIS and maximize the overall oversight capabilities for animal facilities and programs. Relying on the accreditation mechanism and the sanction of withholding federal research funds in those areas where they are naturally effective, should allow allocation of APHIS resources for areas where they are most needed.

3. Compliance by research entities with the accreditation requirement (title II, sec. 202, paragraph (C))

It is the intent of this section to allow research entities to comply with the requirement for accreditation within a time frame comparable to normal facility modernization and/or replacement cycles. By allowing research entities to combine their modernization planning with steps to achieve laboratory accreditation, the Committee hopes to achieve maximum efficiency of resource investment.

Almost one quarter of existing research entities are already accredited on a voluntary basis by the American Association For Accreditation of Laboratory Animal Care (AAALAC), a widely respected laboratory accreditation organization. This number includes medical centers, entire campuses, and a number of veterinary schools. The choice of this mechanism by many institutions reflects the growing realization that investment in excellent animal care and careful evaluation of animal research programs pays off in the resulting excellent and reliable science, good and economical animal hygiene, and clearly understandable assurances to the public of high levels of concern for animal care and treatment. The Committee recognizes AAALC as the kind of organization that can fulfill the criteria of Section 202, and regards it as evidence for the feasibility and effectiveness of the accreditation mechanism. The Committee stresses that other accrediting organizations may exist or be organized to fulfill the purposes of Section 202, and intends that the Secretary be open to certification of any that can meet the criteria of that Section.

AAALAC uses the "Guide for the Care and Use of Laboratory Animals", (DHEW 78–23, 1978 and subsequent revisions) as its primary standard for evaluating facilities and programs. It is intended that during the 10-year period to obtain accreditation, research entities show substantial progress toward achieving both the required and recommended levels for animal care, treatment, and use as specified in the Guide as quickly as possible without placing extraordinary financial burdens on these research entities. The Committee intends that any accrediting agencies seeking certification use as a primary standard either the Guide or similar documents suitable for animals in environments other than the laboratory. The crucial factor is that the detailed standards of the accrediting agencies be open for public scrutiny, and represent the product of careful scientific and public input on acceptable animal care and treatment. In special cases where the care and handling of particular species are covered by other federal statutes (as in the Marine Mammal Protection Act), the Secretary shall insure that accrediting agencies' standards complement those in the relevant statutes, or are more rigorous in areas of obvious need as indicated by this statute or otherwise, and in any case do not contradict standards already in law.

It should be noted that the NIH Guide for laboratory animal care is periodically revised and updated to reflect current knowledge about animal care, treatment, and use in research; thus the Committee intends that any standards promulgated by the Secretary or others should reflect the most current revisions available of this guide and similar documents.

The Committee notes that there are some classes of animal research supported by Federal awards which may not truly fit into a "laboratory animal" definition. Where appropriate, the Committee intends that the Secretary shall identify and certify accreditation systems appropriate to these particular environments. The Committee also has made clear in Title IV that the bill covers only birds and mammals used in research in laboratory or other confined environments. Thus research on birds and wildlife in preserves or other natural settings would be exempted.

4. The role of the animal studies committee in reviewing ongoing research methods and practices (sec. 203, paragraph (a), subparagraph 2(A)(iii))

It is intended that the review by the Animal Studies Committee of ongoing research methods and practices recognize the need for flexibility in evolving experimental design as results are obtained. The normal process of change and refinement that occurs over the course of a research project, as normally allowed by funding agencies, should not be arbitrarily inhibited. Principal investigators should be able to deviate, even substantially, from their original proposal if warranted by their results from previous experiments, as long as these changes still conform to accepted standards for appropriate animal care, treatment and use. It is the role of the Animal Studies Committee principally to monitor conformity with those accepted standards. It is not intended that the Committee's activities supplant or interfere with the normal peer review process.

5. Waiver of accreditation requirements (title II, sec. 203, paragraph (d))

The Committee intends that a waiver of the accreditation requirement for a research entity not be granted without a thorough review of the circumstances for the waiver. It is intended that in a medical emergency or similar situation where important research results are urgently needed, a waiver of the accreditation requirement for the entity carrying out this important research would be appropriate on a temporary basis.

6. Definition of "animal" (title II, sec. 205, paragraph (3))

The term "animal" as used in this act is not intended to include human beings.

7. Definition of direct use of conscious animals (title II, sec. 205, paragraph (5))

"Direct use of conscious animals" is intended to define those users where animals are subjected to more than momentary minor pain or discomfort or where animals are not anesthetized throughout the entire course of a surgical or other invasive procedure. Clearly, direct use would exclude those instances where animals are used for cells or tissues or for procedures such as routineb lood collection, physical examination or nutritional studies. Neither would it apply where animals are used for terminal surgical procedures. This definition is meant to apply only where animals would suffer severe or lengthy pain or, in the case of behavioral studies, where they cannot escape from noxious stimuli.

Examples of direct use of conscious animals would include: 1) chronic, long-term invasive surgical procedures; 2) administration of toxic or caustic substances; 3) painful, experimentally-induced disease (cancers, infectious diseases, etc.); 4 application of painful or noxious stimuli or confinement in painful or uncomfortable environments or positions; 5) learned, enforced, or induced helplessness.

8. Involvement of the veterinarian (title III, sec. 301, paragraph (2))

The Committee intends that a doctor of veterinary medicine be consulted in the planning of experiments that would involve long-term invasive surgical procedures. Examples might include: bone or tooth

implants, cardiac prosthetic devices, organ transplantation, severance of neurological function, or other major procedures. A veterinarian should also be consulted to at least review written protocols wherever direct use of conscious animals is contemplated. It is not intended that a veterinarian be involved where animals are being utilized for tissues or where animals are being subjected to only momentary minor pain or discomfort such as in blood collection or antiserum production. Neither does the Committee intend that a veterinarian must be involved, although in some cases it would be desirable, where animals are being used in experimental surgical or other procedures from which they will not recover.

It is hoped that the veterinarian in the above cases will have some familiarity with laboratory animal medicine (that is either be certified or be eligible to be certified by the American College of Laboratory Animal Medicine). However, the Committee realizes that this may not be possible in view of the limited pool of board-certified or board-eligible veterinarians in this specialty field. It would, however, be in the interests of both good science and good animal care to have veterinarians interested in and experienced in animal research as consultants to research projects.

9. *Use of anesthetics, analgesics, and tranquilizers (title III, sec. 301, paragraph (3))*

The proper use of anesthetics, analgesics, and tranquilizers is necessary for both humane and scientific reasons. In general, the attending veterinarian should use professional judgment as to the choice, route of administration, dose, etc., of the most appropriate drug(s). Research personnel must have guidance and consultation regarding the selection and use of these drugs. Muscle relaxants and paralytic drugs are not anesthetics and should not be used alone for surgical restraint. It should be clear that paralytics may not be used to prevent an animal from demonstrating the presence of pain. In appropriate circumstances, where scientifically necessary, they may be used for surgery in conjunction with known analgesic or anesthetic drugs.

In the unusual case where the use of any anesthetics, analgesics, or tranquilizers would defeat the purpose of an experimental procedure, this procedure may be conducted without these drugs. However, it is intended that any such procedure be directly supervised by the principal investigator and that animals used in this manner only have these drugs withheld for the time necessary to complete the experiment.

10. *Use of animals for multiple survival surgery (title III, sec. 301, paragraph (4))*

The Committee realizes that there are cases where, in the interests of science, it is necessary to use an animal for more than one major operative procedure from which it is allowed to recover. Such cases may include research on rare, threatened, or endangered species where conservation of the existing animals is of utmost importance. Under such conditions, it is intended that animals used for multiple-survival surgeries be accorded adequate anesthesia and post-surgical care including adequate analgesia for relief of post-surgical pain. The Animal Studies Committee may also determine other special circumstances where multiple-survival surgeries on one animal are scientifically necessary and appropriate, however, cost alone is not a justification for such action.

11. Farm animal exemption (title IV, sec. 401(a))

The Committee intends that while horses, livestock, or poultry used for the production or improvement of food or fiber may be housed or cared for under less stringent conditions than laboratory animals, the housing and care of farm animals in facilities accredited under sec. 202 of this act should meet the standards prevailing on a high quality, well managed farm. Such standards are promulgated by State agricultural extension services and land-grant universities. In any case, the Committee intends that where horses, livestock, or poultry are used as experimental animals, they shall be accorded adequate anesthesia or analgesia where painful procedures, including surgery, are employed. The Committee intends that where horses, livestock, or poultry are used for biomedical research on human diseases, or for testing the safety of food for human consumption, these animals shall be cared for and used according to the provisions of this act. For the purposes of this act, horses and other farm animals used for display, exhibition, and competition including races shall be considered as falling under the exemption of Title IV.

12. Wild animal research exemption (title IV, sec. 401(a))

The Committee specifically intends to exempt from the accreditation requirements and other provisions of the Act the research activities of zoos, marine mammal exhibitions, and fish and wildlife agencies or management organizations insofar as these activities are intended to improve wild animal conservation, propagation, and management. The management of many of these animals is already governed by various federal statutes and regulations. However, research experimentation or testing on wild animals used as models for studies concerning human health or to accomplish other goals unrelated to conservation, propagation, or management of the particular or related wild animal species shall not be exempt.

Specific examples of research related to wild animals to be exempted are:

Animal damage control where research is carried out on ways to reduce predator damage.

Environmental contaminants research where animals are live trapped and released after blood samples and other tests are performed to determine the impact of environmental contaminants.

Disease research in which geese, birds, and rats are innoculated with known diseases so that their effects and treatments can be tested as a way of improving control of wild animal disease.

Migratory bird tagging programs.

Endangered species propagation programs including artificial insemination.

Pittman-Robertson research programs conducted in States and the Fish and Wildlife Cooperative Units program (conducted at various universities) under which wildlife research is carried out.

Toxicology research on fish where rats are used to test the impact of environmental contaminants on fish.

Pribilof Islands research program to determine the health of the Pribilof Islands fur seal population.

IV. SECTION-BY-SECTION ANALYSIS

Section 1 provides that this Act may be cited as the "Humane Care and Development of Substitutes for Animals in Research Act".

Section 2 sets out the findings of the Congress pointing to the need for this Act.

Title I—Development of Improved Research and Testing Methods

Section 101 authorizes the Secretary of Health and Human Services to make awards to develop methods of research, experimentation, and testing that do not require live animals, reduce the number of animals used, or produce less pain and distress in such animals, and to establish the validity and reliability of such methods. No award may be made under this section unless a proposal therefor has been assessed through applicable peer review.

The Secretary shall designate an Advisory Panel to provide advice concerning his responsibilities under this title, and to design and recommend a system for insuring that any proposal meeting the requirements of this title will receive full consideration for funding by all appropriate programs of the Department of Health and Human Services, or from resources made available under this title. Funds for making awards under this section shall be made available from research resources within the Department of Health and Human Services.

Section 102 provides for promotion by the Secretary of Health and Human Services through coordination and consultation with the Food and Drug Administration, National Toxicology Program, Environmental Protection Agency and other appropriate agencies, of new or improved non-animal testing methods and of international research and development programs leading to more effective toxicologic data systems. The Secretary shall direct the National Toxicology Program to significantly increase its resources for research and development on new methodologies and validation of non-animal research and testing methods. The Secretary shall submit a report on these activities no later than two years from the date of enactment of this Act and biennially thereafter.

Title II—Federal Award Requirements

Section 2011 provides that no Federal agency shall conduct within its own research entities or approve any research entity for an award unless the research entity is accredited and has provided certain assurances to the appropriate awarding agency.

Section 202 provides that in order to be eligible for a Federal award for research, experimentation or testing involving large numbers of animals, a research entity must be accredited for such activities by a recognized private accrediting agency approved by the Secretary. Such an agency must be able to assess the qualifications, background and experience of research entities in animal use; must have set forth standards at least comparable to the best of current practices, as stated in the National Institutes of Health "Guide for the Care and Use of Laboratory Animals"; must have a system for initial accreditation and routine inspection for reaccreditation both of which must include a

mechanism for monitoring the correction of items of non-compliance and must have a mechanism for liaison with the Institutional Animal Studies Committee.

Full accreditation may be achieved over a period of 10 years as far as needed structural changes and modernization of facilities are concerned, and a research entity may be provisionally accredited if it demonstrates satisfactory progress toward the 10 year goal. However, during the interim period the entity must meet standards for animal care and treatment under the existing Animal Welfare Act, and must comply with appropriate requirements for feeding, watering, shelter, exercise, etc., and acceptable procedures of anesthesia set forth in this Act.

Section 203 provides that the research entity shall, as a condition for the receipt of Federal award for research, experimentation or testing using large numbers of animals, provide a statement of assurances demonstrating that: (1) the research entity has established an institutional animal studies committee including 1 veterinarian and 1 member not affiliated with the research entity who represents community concerns regarding the welfare of the animal subjects; (2) this committee meets regularly and makes inspections of all animal study areas and facilities at least semiannually; (3) this committee reviews research methods and practices in progress involving the direct use of conscious animals for compliance with the original approved proposal or with accepted standards for animal care and treatment; and, (4) this committee has submitted to the responsible Federal agency certification of the above inspections and reviews and of any violations of these assurances.

Reports on these inspections and reviews will be signed by a majority of the committee, and will include any minority views. If either the veterinarian or non-affiliated member do not sign the majority report, they shall be given the particular opportunity to file a minority report. Records of inspections, meetings, etc., will be maintained for at least 3 years. The Committee shall provide instruction and training for scientists and other personnel in various aspects of animal use.

The Committee members are encouraged to notify, in writing, the Animal and Plant Health Inspection Service of the Department of Agriculture, the sponsoring agency and the accrediting agency of any unacceptable conditions not reported in writing by the committee as a whole. The sponsoring Federal agency shall suspend or revoke Federal support for projects in cases where it has determined that the conditions of animal care or treatment have been persistently unacceptable despite notification to the research entity. Research entities shall instruct their employees to report violations to the Animal Studies Committee and shall not discriminate against any employee reporting any such violation. The Secretary may waive the accreditation requirement under exceptional circumstances related to either the research results or the research entity.

Section 204 provides for the establishment of a clearinghouse for information on animal care standards to facilitate agency compliance with this title.

Section 205 defines several important terms.

(1) the term "Federal agency" is defined as in Section 105 of Title 5, United States Code.

(2) The term "responsible Federal agency" means the agency from which the research entity has received or may receive an award for research, experimentation or testing involving the use of animals.

(3) The term "Federal award for the conduct of research, experimentation or testing involving the use of animals" means any mechanism under which Federal funds are provided to support such research.

(4) The term "animal" is defined as any living, warm-blooded animal, that is, birds and mammals.

(5) The term, "research entity" means any school (except an elementary or secondary school), institution, organization or person that uses or intends to use live animals in research, tests or experiments, and that is eligible to receive funds under any mechanism from a Federal agency for the above purposes.

(6) The term "direct use of conscious animals" is defined as any use involving more than momentary minor pain or discomfort or any procedure other than where the animal is naesthetized throughout the entire course of the procedure.

(7) The term "large numbers of animals" is defined as more than 100 rodents, more than 10 nonrodent species and more than 1 nonhuman primate.

Section 206 sets forth the effective date of this title which is three years after the date of enactment of this Act.

Title III—Special Procedures

Section 301 provides that no research entity can receive an award for animal research or testing from a Federal agency unless the agency's scientific review finds that the award proposal includes (1) a justification of the anticipated animal distress involved in terms of the benefits of the research, (2) assurances that a veterinarian has been consulted in the planning of any research or testing involving direct use of conscious animals, long-term invasive or painful procedures, (3) assurances that anesthetics, analgesics, tranquilizers and paralytics have been appropriately used and that the withholding of these drugs for reasons of scientific necessity will only continue as long as necessary and, (4) assurances that, except for reason of scientific necessity, or other special circumstances as determined by the animal studies committee, no animal will be used for more than one major operation from which it recovers.

Section 302 applies the definitions in Title II to this title.

Section 303 sets forth the effective date of this title which shall be one year after the enactment of this Act.

Section 304 sets forth a provision for a Congressional veto over any regulation promulgated by this Act within 60 days of its proposal.

Title IV—Exemptions

Section 401(a) provides an exemption from the provisions of this bill for horses, livestock or poultry used in research, experimentation or testing intended to improve the quality or safety of food, including fish, or fiber, or to improve animal nutrition, health, breeding, etc. This Title also provides an exemption for research intended to improve wild animal conservation or propagation.

Section 401(b) provides for an exemption for specific experiments, programs or facilities for which the provisions of this Act would present specific risks to national security or manned space flight. In order

to obtain such an exemption the responsible agency head must certify to the Secretary of Health and Human Services that such risks are involved along with reasons and justifications. All such exemptions must be recertified annually and be available in an unclassified form for public review.

Title V

Section 501 provides that a review and re-enactment of this Act shall be required in ten years.

V. IMPACT ON INFLATION

In accordance with Clause 2(l)(4), Rule XI of the Rules of the House of Representatives, the following statement is made concerning the inflationary impact of H.R. 6928.

H.R. 6928 is assessed to have no inflationary effect on prices and costs in the operation of the national economy.

VI. COMMITTEE OVERSIGHT FINDINGS AND RECOMMENDATIONS

Pursuant to Clause 2(l)(3), Rule XI of the Rules of the House of Representatives, and under the authority of Clause 2(b)(1) and Clause 3(f), Rule X, the Committee's oversight findings and conclusions are reflected in the recommendations found in the present bill and report.

VII. SUMMARY OF GOVERNMENT OPERATIONS COMMITTEE FINDINGS AND RECOMMENDATIONS

Pursuant to Clause 2(b)(2), Rule X, and Clause 2(l)(3), Rule XI of the Rules of the House of Representatives, no findings or recommendations have been submitted by the Committee on Government Operations for inclusion in this report.

VIII. BUDGET ANALYSIS AND PROJECTION

H.R. 6928 provides no new budget authority or tax expenditures. Consequently, the provisions of Section 308(a) of the Congressional Budget Act are not applicable.

IX. CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, D.C., August 18, 1982.

Hon. DON FUQUA,
Chairman Committee on Science and Technology,
U.S. House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: Pursuant to Section 403 of the Congressional Budget Act of 1974, the Congressional Budget Office has reviewed H.R. 6928, the Humane Care and Development of Substitutes for Animals in Research Act, as ordered reported by the House Committee on Science and Technology on August 11, 1982.

The purpose of this bill is to promote the development of non-animal methods of research and to assure humane care of animals used in scientific research. The bill would require research entities to

be accredited in order to be eligible to receive a federal award for research involving a large number of animals. The standard for accreditation would be comparable to the best of current practices as stated in the National Institutes of Health (NIH) Guide for the Care and Use of Laboratory Animals. Full accreditation could be achieved over a ten year period provided that the research entity demonstrated reasonable progress and that it maintained standards for animal care. In addition, the bill would require the Secretary of Health and Human Services to designate an advisory panel to examine issues involving animal research. The Secretary would be required to report to Congress biennially his progress in this area. Finally, research entities would have to report semi-annually to their responsible federal agency on the status of inspections and reviews of animal research. The authority of this bill would expire ten years after enactment.

Currently, 171 of the non-federal research entities that conduct animal research for the federal government are fully accredited and another 29 are partially accredited. These 200 laboratories receive 45 percent of the federal dollars which go to animal research in non-federal laboratories. The other 460 non-federal laboratories which receive federal funding are not currently accredited. One possible outcome of this bill is that the smaller laboratories would cease to conduct federally supported research and that either the larger laboratories which are currently accredited would conduct more of the research or that animal research would decline.

Researchers at NIH estimate that the cost to research entities for accreditation would be $500 million in total or about $50 million over the ten year life of this bill. Also, about 1,300 additional staff would be necessary to meet the reporting requirements of this bill. Using an average cost of $50,000 per employee, the cost to the research entities for additional manpower would be $65 million per year. NIH would require 5 additional staff at a cost of $250,000 per year.

The cost of this bill to the federal government is unclear, as there is no specific authorization. Research entities that chose to meet accreditation standards might absorb these costs or might seek funding from other sources. The costs to NIH might also be absorbed within current appropriation levels. If, however, appropriations were increased to accommodate some or all of the costs to both the research entities and NIH, outlays would also increase.

Sincerely,

RAYMOND C. SHEPPACH
(For Alice M. Rivlin, Director).

X. CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with Clause 3 of Rule XIII of the Rules of the House of Representatives, it is hereby stated that no changes to existing law result from H.R. 6928.

XI. COMMITTEE RECOMMENDATION

A quorum being present, the Committee ordered H.R. 6928 reported without amendment by voice vote of those present on August 11, 1982.

XII. DISSENTING VIEWS OF HON. F. JAMES SENSENBRENNER, JR., HON. EDWIN B. FORSYTHE, AND HON. HAROLD L. VOLKMER HUMANE CARE AND DEVELOPMENT OF SUBSTITUTES FOR ANIMALS IN RESEARCH ACT (H.R. 6928) AUGUST 11, 1982

I must, respectfully, disagree with the decision of the Committee to approve H.R. 6928. While the goals of this legislation are laudable, its language is vague and overbroad, and its implementation costs, at a time when research funding is being decreased, will necessitate the curtailment of numerous medical and scientific research programs with the resulting imposition of higher medical costs upon our society.

The Issue presented by this legislation is whether enactment would impede the advancement of the public health and the enhancement of human life by requiring that a large portion of the funds used for this purpose be diverted toward the compliance costs of this legislation. I must, respectfully, disagree with my colleagues and answer this question in the affirmative.

Unfortunately, the emotional fervor of the organizations with an interest in this legislation and the resulting political pressure, has clouded the issue presented by this legislation.

Instead the focus has been on two areas of concern: One, the humane treatment of animals, and two, whether alternative treatment methods to the use of live animals should be encouraged. In addressing the first concern, it should be apparent that accurate and valid scientific data cannot be derived from unhealthy or abused animals. As to the second concern, science is constantly searching for more improved and precise methodology.

The overriding goal of scientific and medical research must be the protection and the enhancement of human life. The achievement of this goal is heavily dependent upon the development of new drugs and therapeutic modalities which almost always require the utilization of animals for experimental purposes. It would have been impossible to develop the highly successful coronary bypass operation, which is performed an estimated 50,000 times annually, thereby relieving thousands suffering from pain and for many, prolonging their lives, without the use of animal models. Cancer, which ranks second, has been alleviated, in some cases, by chemotherapeutic agents, which were all tested in animals for signs of toxicity. It should be noted that since 1901, 41 Nobel Prizes in physiology and medicine have been awarded on the basis of studies which involved the use of experimental animals. To alter the methods by which medical research is conducted, as proposed by this legislation, is of grave concern to me.

Section 101(a), of H.R. 6928, authorizes the Secretary of Health and Human Services to make awards for research and development of

alternative methods of research and testing which do not use animals. Section 101(d), requires the Secretary to make the awards from the existing budgetary resources within the Department of Health and Human Services. Therefore, if the research budget of the Department was to remain constant, which is highly speculative in light of our present economic condition, the existing medical and scientific research awards will have to be cut to permit the issuance of these new awards.

Existing medical and scientific research will not only suffer as a result of the foreseeable reduction in the awarding of research grants by the Department of Health and Human Services, but also as a result of the compliance costs required by this legislation. Section 201 provides that no Federal research, or research grant, shall be made unless that research entity is accredited for animal experimentation by the accrediting body and has provided to the Federal agency a statement of assurances. It is estimated that an inspection, required for accreditation, would cost an institution about $1,500, every three years. For example, the University of Wisconsin would incur, for its 12 facilities, $18,000, every three years for inspection of its facilities. In addition, these facilities would incur the additional expense of modifying their facilities to comply with the requirements of the accrediting authority. These costs have been estimated to be $500 million, which will have to be borne exclusively by the research institutions. Though these costs will be incurred over a 10 year period, thereby resulting in an estimated $50 million per year cost for institutional improvements, it will still be an economic hardship for these institutions that will require the reduction or elimination of existing medical and scientific research projects. Further, all of the aforementioned costs will eventually be passed on to the public in the form of higher taxes and higher medical bills. The $\frac{1}{2}$ billion cost of this bill and the increased doctor's bills and the Medicare and Medicaid taxes, cannot be justified.

Finally, I am concerned that the institutional animal studies committee, required by Section 203, will delay or inhibit medical and scientific research. This provision will not only require the expenditure of additional sums by the research institution for the formation and operation of the committee, but will subject the researcher to another review entity, thereby requiring the expenditure of additional time and the creation of additional paperwork. More importantly, this committee has the potential to exercise peer review authority over proposed projects. Since the committee is composed of members that do not have to have medical or scientific degrees, innovative projects may be inhibited.

For the foregoing reasons, I am opposed to the action of the Committee.

F. JAMES SENSENBRENNER, JR.
E. B. FORSYTHE.
HAROLD L. VOLKMER.

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